UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SMITH & NEPHEW, INC., Plaintiff, v. HOLOGIC, INC., Defendant.	Civil Action No. 1:11-cv-12064-NMG **PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION ENJOINING HOLOGIC, INC.'S INFRINGEMENT** ORAL ARGUMENT REQUESTED

MEMORANDUM OF LAW IN SUPPORT OF SMITH & NEPHEW'S MOTION FOR A PRELIMINARY INJUNCTION

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I. INTRODUCTION

Plaintiff Smith & Nephew, Inc. ("S&N") and Defendant Hologic, Inc. ("Hologic") each make, sell, and/or offer to sell medical device systems designed for use by doctors in a procedure for the removal of abnormal tissue masses on the inside of the uterus, which are commonly referred to as "intrauterine fibroids" and/or "polyps." S&N's system, now marketed under the tradename TRUCLEAR™, has been commercially available since 2005 and is widely recognized as a significant innovation in the marketplace for this gynecological procedure. Hologic's system, marketed under the tradename MyoSure®, was first launched in approximately January, 2010.[1]

The method by which the TRUCLEAR™ and MyoSure® systems are used for the removal of intrauterine fibroids and/or polyps is virtually identical. That same method is covered by the claims of U.S. Patent No. 8,061,359 entitled "Surgical Endoscopic Cutting Device And Method For Its Use" (the "'359 Patent"), to which S&N is the sole and exclusive assignee. S&N is entitled to the entry of a preliminary injunction enjoining Hologic from engaging in infringing activities at least because:

- *S&N will likely prevail on the merits of its case*. There is no real question that Hologic promotes use of its MyoSure® System for an infringing purpose. Further, even Hologic admits that the patented method was an innovation invented by Dr. Mark Hans Emanuel, the named inventor of the '359 Patent, and it is unlikely that Hologic will be able to meet its burden of proving the '359 Patent to be invalid.

- *S&N's gynecology business will be irreparably harmed by Hologic's continued infringement*. The TRUCLEAR™ and MyoSure® Systems compete directly. Hologic's established presence as a respected provider of women's health products is a significant competitive advantage over S&N, which is known primarily as a provider of medical devices in areas outside of gynecology. In addition to lost sales, every day that Hologic's infringing MyoSure® System competes directly with the

[1] Hologic's MyoSure® System was originally launched by a company called Interlace Medical, Inc. ("Interlace"). Hologic acquired Interlace in January, 2011.

> TRUCLEAR™ System is an additional day in which S&N is unable to establish itself as a respected brand name and innovator in the market for these devices. This loss of opportunity and goodwill is virtually impossible to calculate in a way that could fully compensate S&N for the damage caused by Hologic's continued infringement.

The balance of hardships and the public interest also both weigh heavily in favor of an injunction. Accordingly, pursuant to Federal Rule of Civil Procedure 65(a) and 35 U.S.C. § 283 and as set forth further herein, S&N respectfully requests that this Court enter an order enjoining Hologic from making, using, selling or offering for sale its MyoSure® Tissue Removal Device ("MyoSure® TRD") in combination with its MyoSure® Rod Lens Hysteroscope ("MyoSure® Hysteroscope") (collectively the "MyoSure® System"), or any other products not more than colorably different therefrom, which directly and indirectly infringe the '359 Patent.

II. STATEMENT OF FACTS

A. S&N, and the Patented Technology.

For more than 150 years, S&N has developed and sold advanced medical devices enabling medical professionals to provide effective treatment more quickly and economically. Flores Decl. Ex. B.[2] Among other areas, S&N has a well-established reputation as an innovator in the field of arthroscopy (minimally invasive surgery on joints), creating new devices and techniques that enable surgeons to operate effectively and carry out procedures that were not previously possible. *Id.* However, prior to the launch of the TRUCLEAR™ System, S&N did not have any business directed towards women's health or gynecology. Sahney Decl. ¶3.[3] That changed after S&N acquired the patent rights to the '359 Patent in 2000.

[2] The term "Flores Decl." refers to the Declaration of Michelle A. Flores In Support Of Smith & Nephew, Inc.'s Motion For A Preliminary Injunction, filed concurrently herewith.

[3] The term "Sahney Decl." refers to the Declaration of Mira Sahney In Support Of Smith & Nephew, Inc.'s Motion For A Preliminary Injunction, filed concurrently herewith.

The '359 Patent is directed to a method for the removal of tissue from a uterus, such as fibroids or polyps. The presence of intrauterine fibroids and/or polyps is a potential cause of abnormal uterine bleeding. As many as one in ten women suffer from heavy and/or abnormal menstrual bleeding ("menorrhagia"). Flores Decl. Ex. C at p.1. In fact, it is one of the most common complaints encountered by primary care physicians and gynecologists, affecting more than 10 million women annually. *Id.* Although menorrhagia is not fatal, it severely impacts the quality of life of the women who suffer from this condition. Some of the symptoms associated with menorrhagia include menses that continue for more than seven days, chronic anemia, pelvic pain and cramping. *Id.* Intrauterine fibroids (i.e. myomas) and endometrial polyps are two common non-hormonal causes of menorrhagia. *Id.*

Until recently, the primary treatment for menorrhagia caused by fibroids or polyps involved major invasive surgery, such as dilation and curettage (i.e. D&C) or a hysterectomy. *Id.* at p. 2. Hysteroscopic myomectomy[4] by use of a resectoscope has become another effective treatment option. *Id.* Currently, the most popular hysteroscopic tools for removing fibroids and polyps are monopolar and bipolar loop resection devices. *Id.* Other radiofrequency ("RF") ablation devices that employ high-frequency electrical current are also used to treat abnormal uterine bleeding. Flores Decl. Ex. D at p.1.

Conventional hysteroscopic resection procedures using pre-existing "loop resector" technology carry a number of disadvantages and risks. For example, the surgeon periodically must remove these instruments during the procedure in order to insert a suction device into the

[4] The dictionary defines the term hysteroscope as "an endoscope used for the visual examination of the cervix and interior of the uterus." MERRIAM-WEBSTER DICTIONARY, *available at* http://www.m-w.com. The dictionary defines myomectomy as "surgical removal of a myoma or fibroid." *Id.*

uterus to remove the resected tissue and clear the visual field. Flores Decl. Ex. C at p.2. Consequently, the surgeon inserts and removes the surgical instruments numerous times, which prolongs the duration of the procedure and increases the risk of injury. *Id.* Although these devices provide good clinical results, their use is associated with the following risks: excessive intravasation of distention fluid (i.e. fluid overload), which may be life threatening; misdirected RF energy and possible perforation of the uterus; uncontrolled monopolar leakage of electrical current, which may cause tissue burns; obscured visual field due to debris tissue resulting from resection; and uterine perforation or cervical laceration caused by repeated removal and reinsertion of surgical instruments. Flores Decl. Ex. C at p.2; Ex. D at p.1.

To overcome the failings of these prior art devices and methods, Dr. Mark Hans Emanuel invented a mechanical hysteroscopic morcellator[5] for the removal of uterine fibroids and polyps. Flores Decl. Ex. A; Ex. E at p.3. On September 4, 1997, he filed the first of several patent applications in his home country the Netherlands. Flores Decl. Ex. A. The '359 Patent claims priority to that patent application and covers Dr. Emanuel's invention.[6] *Id.* The United States Patent and Trademark Office issued the '359 Patent on November 22, 2011. The '359 Patent is generally directly to the use of a hysteroscope and a motor-driven cutting device for the purpose of removing tissue from a uterus. *Id.* More specifically, the claims of the '359 Patent generally recite a method of removing tissue from a uterus by inserting an endoscope with specific physical features into the uterus, followed by inserting a motor-driven cutter into the endoscope

[5] The dictionary defines the term morcellation as "division and removal in small pieces (as of a tumor)." MERRIAM-WEBSTER DICTIONARY, available at http://www.m-w.com.

[6] The '359 Patent is a continuation of U.S. Patent Application No. 09/486,977, which issued on July 31, 2007 as U.S. Patent No. 7,249,602 ("the '602 Patent"). *Id.* The '602 Patent is the national stage entry of PCT/NL98/00504 filed on September 4, 1998, which claims priority to NL Patent No. 1006944 filed on September 4, 1997. *Id.*

such that it extends into the uterus, delivering fluid through the endoscope into the uterus, energizing the motor to drive the cutter and to cut tissue within the uterus, and removing cut tissue and fluid through the cutter. *See e.g.*, *id.* at claim 1.

The method claimed by the '359 Patent has several significant advantages over the prior art techniques, including 1) reduced operating time, resulting in less patient exposure to anesthesia and less risk of fluid overload; 2) single entry of surgical instruments during the procedure, resulting in less risk of uterine puncture and cervical laceration; 3) no use of RF, which eliminates the risk of thermal injuries or burns; 4) instantaneous removal of resected tissue, which facilitates visualization of the of the operative field; and 5) shorter patient recovery time. *See* Flores Decl. Ex. C; Ex. D at p.4; and Ex. E at p.3.

As a direct result of these advances, physicians and others in the medical industry have recognized that "[m]orcellator hysteroscopy is at the forefront of what will become a new, less invasive standard of care for treating menorrhagia caused by myomas and polyps." Flores Decl. Ex. C at p.1; *see also* Stone Decl. ¶6[7]. Indeed, Hologic's own marketing materials acknowledge that this innovative technology is "the way of the future" and credit Dr. Emanuel as its inventor. Flores Decl. Ex. E at pp. 3, 5. For example, a video prominently displayed on Hologic's website, entitled "Hysteroscopic Myoma Resection: The Next Generation," explains:

> To overcome these failings [of the prior art techniques], Dr. Mark Hans Emanuel from the Netherlands invented a hysteroscopic morcellator which was introduced to the US market in 2004. Unlike the traditional resectoscope, this device allowed for the removal of uterine pathology using only normal saline thereby obviating the concerns associated with non-ionic distention media. While this technology has proven safe and provided answers to several nagging issues with loop electrode resectoscopy … .

[7] The term "Stone Decl." refers to the Declaration of Dr. David A. Stone In Support of Smith & Nephew, Inc.'s Motion for a Preliminary Injunction, filed concurrently herewith.

> In summary, given the patient safety limitations of loop electro-resectoscopy and the dramatic improvements in hysteroscopic morcellation capabilities, we believe that this newer technique is the way of the future."

Id.

The ground-breaking nature of Dr. Emanuel's invention is further evidenced by the "Best Inventor of the Year" he received in 1999. Flores Decl. Ex. G at p.5 (awarded by Innovation Center for Inventions, ID-NL, a government organization). "Based on the creative leap, economic importance and innovative value, this invention was chosen from a total of hundreds of inventions for nomination." Flores Decl. Ex. F at p.3. Of the nominated inventions, Dr. Emanuel was awarded the "main prize." Flores Decl. Ex. G at p.5.

B. S&N's TRUCLEAR™ System

S&N is the sole and exclusive assignee of the '359 Patent. Sahney Decl. ¶4. After acquiring the patent rights in 2000, S&N invested a significant amount of resources to develop a mechanical morcellation system, and launched its first product line directed to gynecological surgical procedures in 2005. *Id.* ¶5. This system is currently marketed, promoted and sold under the brand name TRUCLEAR™, and embodies the claims of the '359 Patent. *Id.*

The TRUCLEAR™ system employs a hysteroscope with multiple channels, a cutting device that can aspirate cut tissue and fluid, and a motor drive control unit (the "TRUCLEAR™ System"). *Id.* ¶6. The individual parts of the TRUCLEAR™ System are used by doctors during procedures for the removal of intrauterine fibroids and/or polyps. *Id.* S&N has not traditionally had much, if any, experience in the gynecology area. *Id.* ¶7. Thus, S&N has recognized that the needs of its gynecology business are somewhat different from those of its other businesses, and that S&N's institutional knowledge and existing relationships with orthopedic surgeons are not particularly relevant to its new gynecology business. *Id.* Its sales/marketing staff who are trained almost exclusively on orthopedic procedures and technology have limited transferable

knowledge that can benefit the gynecology business unit. *Id.* Furthermore, the needs of S&N's gynecology customers are significantly different from those of its other customers, presenting different engineering problems and requiring different research and development solutions. *Id.*

Over the past decade, S&N has expended considerable effort and expense to train physicians and hospitals on the use of mechanical morcellation technology, and in particular, the use of the TRUCLEAR™ System for the removal of intrauterine fibroids and polyps. *Id.* ¶8. In addition to the marketing and selling of the TRUCLEAR™ System, specifically, S&N's efforts and investment have necessarily been directed towards fostering the acceptance of and education about the mechanical hysteroscopic morcellation procedure, generally, within the gynecology market. *Id.* S&N is now beginning to see a return on its investment, as acceptance of the procedure has increased in the gynecology market, and as sales have continued growing. *Id.* ¶9. As more doctors and hospitals learn about the benefits of mechanical hysteroscopic morcellation, S&N's gynecology division has the potential to grow much larger. Going forward, S&N estimates the market for these procedures to be approximately $400 million. *Id.*

C. Hologic's MyoSure System

In January 2010, Interlace began marketing and selling a mechanical hysteroscopic morcellation system under the brand MyoSure®. Sahney Decl. ¶10. Rather than develop its own women's health-related technology, Interlace decided to "build off" S&N's concept of mechanical tissue morcellation. Flores Decl. Ex. E at p.3. In fact, to obtain clearance from the FDA, Interlace indicated that the intended use and operation of its morcellation system is not just substantially equivalent, but identical to S&N's system:

> The principles of operation of the Interlace Medical Hysteroscopic Morcellation System are **identical** to those of the predicate device, the Smith and Nephew Hysteroscopic Morcellation System K041774.
> …

> The Interlace System is substantially equivalent in design, materials, construction and intended use as that of the predicate.

Flores Decl. Ex. H at p.2. (emphasis added).

In January 2011, Hologic purchased Interlace for more than $125 million. Duncan Decl. ¶ 22[8]. Hologic proclaims itself "The Women's Health Company," and is a leading developer, manufacturer, and supplier of advanced medical devices for the treatment of gynecological diseases and conditions. Flores Decl. Ex. I. Since purchasing Interlace, Hologic has marketed, promoted, and sold, and continues to market, promote, and sell the MyoSure® System, including to accounts that presently use the TRUCLEAR™ System. Sahney Decl. ¶11.

The MyoSure® System consists of the MyoSure® Hysteroscope, the MyoSure® TRD that can aspirate cut tissue and fluid, and a motor drive control unit. Flores Decl. Ex. L. Hologic markets, teaches and promotes the use of the MyoSure® System for the removal of intrauterine fibroids and polyps, which Hologic refers to as the MyoSure® procedure ("MyoSure® Procedure"). *Id.* The MyoSure® Hysteroscope has two channels, a sealed optics channel and a hollow working channel. *Id.* The optics channel has a lens at one end and a fiber optics bundle that runs the length of the channel, which when used in the MyoSure® Procedure allows the surgeon to visualize the uterus. *Id.* During the MyoSure® Procedure, the working channel has a valve that is connected to a fluid delivery system, allowing distension fluid to pass through the hollow channel into the uterus. *Id.* When in use, the MyoSure® TRD is connected to a vacuum source, and when its motor is activated simultaneously cuts uterine tissue and aspirates the resected tissue and distension fluid through a window in the device. *Id.* In short, the MyoSure® System and Procedure are the same as the method claimed in the '359 Patent. *Id.*

[8] The term "Duncan Decl." refers to the Declaration of Gregory Duncan, Ph.D. in Support of Smith & Nephew, Inc.'s Motion for Preliminary Injunction, filed concurrently herewith.

Like the TRUCLEAR™ System, the MyoSure® System was specifically designed for the removal of uterine tissue, and it is not cleared by the FDA for any other use. *See* Flores Decl. Exs. H, V. Hologic's website and marketing materials carefully and thoroughly demonstrate to physicians how to use the MyoSure® System to perform the MyoSure® Procedure. *See* Flores Decl. Exs. N, O, P, U. Utilizing its far larger sales force and existing network of customers in the women's health field, Hologic has aggressively marketed and promoted the MyoSure® System. Sahney Decl. ¶11. Many physicians have used and continue to use the MyoSure® System to remove abnormal uterine tissue. Flores Decl. Ex. J at ¶¶ 10, 11, 14; Stone Decl. ¶7.

D. Harm Suffered By S&N As The Result of Hologic's Infringement.

S&N was the first company to offer, make, and sell a mechanical morcellation system for the hysteroscopic removal of intrauterine fibroid and polyps. Sahney Decl. ¶5. "By being first, the firm – at least temporarily – enjoys the freedom to market its offering in the absence of substitutes." Duncan Decl. ¶ 27. Under this reduced competitive pressure, the firm can become established in a market that would otherwise be difficult to enter. *Id.* "As a result, first mover advantage can give rise to long-term differences in firm performance and profitability." *Id.*

S&N and Hologic are direct competitors. Duncan Decl. ¶¶ 7, 8, 20, 25; Stone Decl. ¶5. The TRUCLEAR™ and MyoSure® Systems are the only mechanical hysteroscopic morcellation systems currently marketed or sold for the purpose of removing tissue from inside the uterus. Sahney Decl. ¶12; Duncan Decl. ¶¶ 6, 20. Regardless of any purported difference between the systems as advertised by the parties, both products address the same segment of the market and the procedures are substitutes in that one procedure is chosen over the other.

Thus, it is not surprising that S&N has lost sales of its TRUCLEAR™ System to Hologic's MyoSure® System. For example, the Faulkner Hospital, in Boston, Massachusetts, was a longstanding and very large customer of S&N's TRUCLEAR™ System. Sahney Decl.

¶13. Hologic's predecessor, Interlace, conducted a trial of the MyoSure® Procedure at Faulkner Hospital with a physician it hired as a consultant, Dr. James Greenberg. *Id*. As a direct result of Hologic's interference, S&N's TRUCLEAR™ System was removed from the Faulkner Hospital entirely, and no further TRUCLEAR™ sales have been made that hospital. *Id.* If Hologic is allowed to continue its infringing sales of the MyoSure® System, S&N believes it will continue to lose sales and market share just as it did at the Faulkner Hospital. *Id*. ¶14.

In addition to lost sales, Hologic's entry into the market threatens S&N's future growth and the overall survival of its gynecology business in at least three ways that are very difficult to measure with accuracy. Duncan Decl. ¶ 26. First, the continued presence of the MyoSure® System in the market will prevent S&N from gaining the first mover advantage that it needs to establish a presence both as a new entrant in the women's health segment, generally, and in the market for hysteroscopic morcellation, more specifically. *Id.* ¶¶ 27-42. Second, the dynamic nature of the women's health segment make it likely that other competitors may develop new treatments for abnormal uterine bleeding while the MyoSure® System remains on the market. *Id.* ¶¶ 45-46. S&N's ability to compete and/or maintain a powerful competitive advantage as an innovator for treatments in this market segment would then be lost forever. Finally, the disruption caused to doctors in the event that they purchase the MyoSure® System only to have to remove it as a result of a permanent injunction upon the finding of infringement in this case could irreparably harm S&N's goodwill in ways that are incalculable as a matter of patent damages. *Id.* ¶¶ 43-44.

III. LEGAL STANDARDS GOVERNING PRELIMINARY INJUNCTIONS

The Patent Act provides that a district court "may grant injunctions in accordance with principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. "It is well settled that the granting of a temporary

injunction, pending final hearing, is within the sound discretion of the trial court." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1344-45 (Fed. Cir. 2008) (*citing Deckert v. Independence Shares Corp.*, 311 U.S. 282, 290 (1940)). Although it is an extraordinary remedy, the courts have recognized that the "the purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Id.* at 1344-45, (*citing Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981)).

"The factors the trial court considers when determining whether to grant a preliminary injunction are of longstanding and universal applicability. As the Supreme Court recently reiterated, there are four: '[a] plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of the equities tips in his favor, and [4] that an injunction is in the public interest.'" *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375-76 (Fed. Cir. 2009) (*quoting Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). "These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of relief requested." *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988).

IV. ARGUMENT

A. It Is Highly Likely That S&N Will Prevail On The Merits Of Its Case.

In order to establish a likelihood of success on the merits "the patentee must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). "In assessing whether the patentee is entitled to the injunction, the

court views the matter in light of the burdens and presumptions that will inhere at trial." *Titan Tire*, 566 F.3d at 1376.

1. Hologic Infringes The '359 Patent

A patent owner has the burden of proving infringement, and must meet that burden by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F. 2d 878, 889 (Fed. Cir. 1988). "An infringement analysis proceeds first to claim construction to determine the scope and meaning of the asserted claims, and second to a comparison of the properly construed claims with the allegedly infringing product to determine whether the product embodies every limitation of the claims." *Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1301 (Fed. Cir. 2005). As set in further detail below, the evidence in this case plainly establishes that the use of Hologic's MyoSure® TRD in combination with the MyoSure® Hysteroscope infringes claims 1, 3 and 4of the '359 Patent.[9] *See infra*, p. 13. The evidence also evinces that Hologic is liable for contributing to and inducing others to infringe, because Hologic makes, sells, and offers for sale the MyoSure® TRD and MyoSure® Hysteroscope, which are a material part of the patented process, and instructs and encourages others to use the MyoSure® System in a manner that infringes the '359 Patent.

a. Claim Construction

Claim construction begins with the words of the claims, which "are generally given their ordinary and customary meaning." *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-14 (Fed. Cir. 2005) (en banc); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Indeed, there is "a 'heavy presumption' that a claim term carries its ordinary and customary

[9] For purposes of this motion, S&N only addresses Hologic's infringement of claims 1, 3 and 4 of the '359 Patent. S&N does not waive its claims for infringement of the other claims of the '359 Patent.

meaning." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F. 3d 1313, 1325 (Fed. Cir. 2002). The Federal Circuit has explained "that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313.

Here, none of the asserted claims of the '359 Patent contain any language that requires special construction. The ordinary meaning of each claim term is "readily apparent," and thus claim construction in this matter "involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

b. Use of Hologic's MyoSure® TRD and MyoSure® Hysteroscope Directly Infringes Claims 1, 3 and 4 of the '359 Patent

Based upon the plain meaning of the asserted claims, use of the MyoSure® Procedure directly infringes claims 1, 3 and 4 of the '359 Patent. Hologic has sold both the MyoSure® TRD and MyoSure® Hysteroscope since at least January 2010. *See supra* at p. 7. The MyoSure® System is clearly used by doctors to remove uterine tissue. *See supra* at p. 9. Further, as shown in the attached claim chart and in the accompanying testimony of Dr. David A. Stone, the MyoSure® Procedure literally meets each and every limitation of the asserted method claims. Flores Decl. Ex. L.

c. Hologic's Actions Constitute Contributory Infringement

The Patent Act makes it an act of infringement to offer to sell or sell "a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c) (2006). As previously set forth above, use of Hologic's MyoSure® TRD and MyoSure® Hysteroscope constitutes direct infringement of claims 1, 3 and 4. *See*

supra at p. 13. The MyoSure® System has no use other than for the resection and removal of uterine tissue using the method claimed in the '359 Patent. In fact, Hologic specifically designed, markets and sells the MyoSure® TRD and MyoSure® Hysteroscope with FDA clearance for only this procedure. *See supra* at p. 9. Accordingly, Hologic's MyoSure® TRD and MyoSure® Hysteroscope are non-staple articles that are material components used in the method claimed by the '359 Patent. *Polysius Corp. v. Fuller Co.*, 709 F. Supp. 560, 576 (E.D. Pa. 1989), *aff'd*, 889 F.2d 1100 (Fed. Cir. 1989) ("A non-staple article is one which was designed to carry out the patented process and has little or no utility outside of the patented process"). Each time a physician uses the MyoSure® System to remove intrauterine fibroids or polyps, Hologic is liable for contributory infringement.

d. Hologic Induces Infringement By Its Customers

The Patent Act proscribes indirect infringement by inducement, stating that "[w]hoever actively induces infringement of a patent [by a third party] shall [itself] be liable as an infringer." 35 U.S.C. §271(b). In order to prove inducement, a patentee must show "first that there has been direct infringement, and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 697-98 (Fed. Cir. 2008); *see also DSU Med. Corp v. JMS Co., Ltd.*, 471 F.3d 1293, 1305-06 (Fed. Cir. 2006) (en banc).

As set forth in detail above, the first element of the inducement inquiry -- direct infringement -- is met here. The claim chart and supporting evidence establish that any physician using Hologic's MyoSure® TRD and MyoSure® Hysteroscope directly and necessarily infringes claims 1, 3 and 4 of the '359 Patent. *See supra* at p. 13.

The next element of the inducement inquiry -- "knowingly inducing infringement" -- is also satisfied. Hologic's detailed website and reams of marketing materials carefully and

thoroughly demonstrate to physicians how to use its MyoSure® TRD and MyoSure® Hysteroscope for the removal of intrauterine fibroids and polyps using the method claimed in the '359 Patent. *See supra* at p. 9. There can be no question that Hologic actively encourages physicians to use the accused product in an infringing manner. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851-52 (Fed. Cir. 2010), *aff'd*, 131 S. Ct. 2238 (2011) (holding that online training and user support resources that provide detailed instructions on the use of an accused product were "substantial evidence that [the defendant] intended the product to be used in an infringing manner").

Finally, on November 21, 2011, S&N sent Hologic a cease and desist letter, in which S&N informed Hologic that the PTO would issue the '359 Patent imminently, and demanded that Hologic "cease making, using, selling, or offering for sale its MyoSure® System immediately." Flores Decl. Ex. K. Thus, Hologic has had actual knowledge of the '359 Patent since at least November 21, 2011 upon receipt of S&N's cease and desist letter. At that point, Hologic knew or should have known that its instructions for the use of its MyoSure® TRD and MyoSure® Hysteroscope for the removal of intrauterine fibroids and/or polyps through use of the MyoSure® Procedure would result in those devices being used in an infringing manner. Intent to induce infringement can be properly inferred from an alleged inducer's knowledge of the patent and knowledge of the infringing activities. *See MEMC Elec. Materials, Inc. v. Mitsubishi Material Silicon Corp.*, 420 F.3d 1369, 1379 (Fed. Cir. 2005); *see also i4i Ltd.*, 598 F.3d at 851-52. Therefore, the final element – specific intent – is also met here.

2. <u>There Is No Substantial Question About Validity Of The '359 Patent</u>

"[A] patent enjoys the same presumption of validity during preliminary injunctions proceedings as at other stages of litigation. Thus, if a patentee moves for a preliminary injunction and the alleged infringer does not challenge validity, the very existence of the patent

with its concomitant presumption of validity satisfies the patentee's burden of showing a likelihood of success on the validity issue." *Titan Tire*, 566 F.3d at 1377; *see also* 35 U.S.C. 282.

Hologic has the burden "to come forward with evidence of invalidity." *Id*. at 1377. No prior art references relevant to the '359 Patent have been identified. Given the priority date of the '359 Patent, which is at least as early as September 4, 1997, it is unlikely that Hologic will discover prior art references that are more relevant than those already considered and rejected by the patent examiner at the PTO. In fact, the face of the '359 Patent contains no less than 100 prior art citations. The PTO had sufficient opportunity to reject the claims of the '359 Patent during the more than four years the application was pending, and it did not do so.

Furthermore, Hologic's own words and actions confirm that the method claimed by the '359 Patent is inventive and novel, and credit Dr. Emanuel as its inventor. *See supra* at pp. 5-6. In fact, Hologic is not alone in acknowledging Dr. Emanuel's accomplishment. In 1999, Dr. Emanuel was named inventor of the year for this technology. In addition, the numerous medical periodicals and articles have concluded that hysteroscopic morcellation is the new standard of care for the treatment of menorrhagia. *See supra* at p. 5. In light of the volume and weight of this evidence and in the absence of potential prior art, it is extremely unlikely that Hologic can raise a substantial question of invalidity.

B. S&N Will Be Irreparably Harmed By Hologic's Continued Infringement

For at least the following reasons, Hologic has and continues to irreparably harm S&N by selling its MyoSure® TRD and MyoSure® Hysteroscope.

First, "[w]here failure to grant an injunction would allow a competitor to enter the market, district courts have continued to issue injunctions." *Amgen, Inc. v. F. Hoffman-La Roche, Ltd.*, 581 F. Supp.2d 160 (D. Mass. 2008) (J. Young). Numerous courts have found

irreparable harm "under circumstances where the plaintiff practices its invention and is a direct market competitor" of the defendant's. *Becton Dickinson and Co. v. Tyco Healthcare Group LP*, No. 02-1694GMG, 2008 U.S. Dist. LEXIS 87623, at *9 (D. Del., Oct. 29, 2008) (quotation omitted); *see also Mass Engineered Design, Inc. v. Ergotron, Inc.*, 633 F. Supp. 2d 361, 393 (E.D. Tex. 2009) ("direct competition in a markplace (sic) weighs heavily in favor of a finding of irreparable injury"). Here, S&N and Hologic are not only direct competitors, they are the only competitors in the relevant market – hysteroscopic morcellation. *See supra* at p. 9. According to the Federal Circuit, "the existence of a two-player market may well serve as a substantial ground for granting an injunction – e.g. because it creates an inference that an infringing sale amounts to a lost sale for the patentee." *Robert Bosch LLC v. Pylon Mfg Corp.*, No. 2011-1096, 2011 U.S. App. LEXIS 20700, at *21 (Fed. Cir. Oct. 13, 2011). Therefore, the harm to S&N is irreparable because the vast majority of MyoSure® TRD and MyoSure® Hysterscope sales by Hologic are to the exclusion of S&N sales. *See supra* at pp. 9-10.

Second, by usurping hysteroscopic morcellation technology, Hologic has curtailed S&N's ability to market the use of its TRUCLEAR™ System as a unique innovation. Being an innovator in the medical device industry is extremely advantageous. For example, by being first to the market with this technology, S&N should have enjoyed the freedom to market and sell its TRUCLEAR™ System in absence of substitutes. *See supra* at p. 9. Under this reduced competitive pressure, it is likely that S&N could have firmly established itself in a new market – gynecology. *Id.* Thus, it is not surprising that the "first mover advantage can give rise to long-term differences in firm performance and profitability." *Id.* For this reason, courts have recognized that "where a company pioneers an invention in the marketplace, irreparable harm

flows from a competitor's attempts to usurp the pioneering company's market position and goodwill." *See 800 Adept, Inc. v. Murex Sec., Ltd.*, 505 F. Supp. 2d 1327, 1337 (M.D. Fl. 2007).

Furthermore, each sale lost to Hologic's MyoSure® TRD and MyoSure® Hysteroscope causes further irreparable harm to S&N in the form of lost future sales opportunities. With each sale of its MyoSure® System, Hologic is generating a deeper relationship with its customer. *See supra* at pp. 9-10. As a result, Hologic "gains the ability to market additional products to existing customers at much lower costs than that associated with introducing new products to new customers." *Id.* In fact, Hologic already has a suite of complementary products that it markets and sells with the MyoSure® System to the same customers, giving it yet another competitive advantage over S&N. Duncan Decl. ¶23. Consequently, Hologic's infringement does not only inflict immediate loss in sales and profits on S&N. It also is reshaping the market in ways that will inflict continued long-term irreparable harm. *See, e.g., TiVo, Inc. v. Echostar Commn's Corp.*, 446 F. Supp. 2d 664, 670 (E.D. Tex. 2006) *rev'd on other grounds*, 516 F.3d 1290 (Fed. Cir. 2008) ("[T]he impact of Defendant's continued infringement is shaping the market to Plaintiff's disadvantage and results in long-term customer loss.").

Third, if Hologic's sales of the MyoSure® System are not preliminarily enjoined in this action, S&N will likely experience lost goodwill when S&N succeeds in proving infringement and the MyoSure® System is removed from the market. Both S&N and Hologic engage in training and education as part of their sales process, thus creating brand loyalty. The disruption and loyalty created by Hologic during the pendency of this lawsuit if it were permitted to continue selling the MyoSure® System may result in surgeons and hospitals that are reluctant to switch from the MyoSure® System to the TRUCLEAR™ System when S&N obtains a

permanent injunction. Thus, the more time Hologic is allowed to infringe, the more physicians and hospitals will begin using the MyoSure® System, resulting in more harm to S&N.

Finally, given the dynamic nature of the medical device industry and the women's health segment in particular, it is doubtful that S&N will ever regain the powerful competitive advantage that is afforded by the exclusive right to market and sell products and procedures covered by the claimed methods of the '359 Patent. For example, it is likely that new treatments for menorrhagia could emerge in the market, from as yet unknown competitors. *See supra* at p. 10. If Hologic's infringement continues and additional products for the treatment of abnormal uterine bleeding caused by the presence of fibroids and/or polyps become available, then S&N will lose sales and market share not only to Hologic, but to any new treatments as well. In that case, it would be virtually impossible for S&N to regain the benefits of exclusivity.

C. The Balance of Hardships Weighs Heavily In Favor Of An Injunction

For all the reasons discussed above in connection with the irreparable harm factor, the balance of the hardships strongly favors granting an injunction. *See supra* at pp. 16-19. The hardship imposed on S&N as the result of Hologic's infringing conduct is substantial. *See Bosch*, 2011 U.S. App. LEXIS 20700, at *36 (requiring a patentee to compete against its own patented invention, with the resultant harms – e.g. loss of market share, loss of access to potential customers, and price erosion – "places a substantial hardship on the patentee").

In contrast, Hologic will suffer little if no harm if the Court issues an injunction. The Federal Circuit has long held that "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Windsurfing Int'l, Inc. v. AMF, Inc.* 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986). Hologic cannot rely upon any alleged loss of market share or customer relationships, because "[s]imply put, an alleged infringer's loss of market share and customer relationships

without more, does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct." *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). Therefore, the balance of hardships weighs heavily in favor of issuing a preliminary injunction.

D. The Public Interest Favors An Injunction

The public interest favors the issuance of a preliminary injunction in this case. First, "the public is best served by enforcing patents that are likely valid and infringed." *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006). Indeed, as the Federal Circuit has expressly acknowledged, "a preliminary injunction that enforces a valid patent against an infringer 'does no more than further public policy inherent in the patent laws designed to encourage useful inventions by rewarding the inventor with a limited period of market exclusivity.'" *Pfizer*, 429 F.3d at 1382 (citation omitted). Because S&N has established a likelihood of success on the merits, an injunction will in fact advance the public interest.

Furthermore, any disruption to hospitals or physician's practices caused by a preliminary injunction will be significantly less now than at a later stage. For example, if Hologic's infringement is allowed to continue, "disruption will result in not only the hospitals presently using [t]he device, but in addition, all of the hospitals which may be persuaded to begin using it between now and trial." *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, No. 93-108, 1993 U.S. Dist. LEXIS 19959, at *31-32 (D.Del. July 16, 1993) (finding that "such disruption will be minimized by granting the preliminary injunction").

V. CONCLUSION

For the foregoing reasons, S&N respectfully requests that the Court grant its present motion for a preliminary injunction in a form consistent with the [Proposed] Order filed herewith.

November 23, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on November 23, 2011.

/s/ Maia H. Harris
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